



Department of Health

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New York State Tissue Resources Program

Policy – Determining donor acceptability for donors of birth tissues

Effective Date – December 4, 2023

Valid until – Regulatory or policy change supersedes this policy

10 NYCRR Section 52-3.3(e)(1) requires that living donors and their tissue be found acceptable by the medical director prior to retrieval of tissue. Under Section 52-3.3(d), the acceptability of a donation from a living donor shall be determined by a physical examination of and health history interview with the donor.

When birth tissue, including amniotic membrane, chorion, placenta, and umbilical cord tissues, is collected from an individual incidental to giving birth, the requirement of 10 NYCRR Section 52-3.3(e)(1), that the living donor and their tissue be deemed acceptable prior to retrieval of the tissue, may not be practicable. This policy document is to clarify that in such instances, rather than determining acceptability prior to retrieval, the tissue bank may determine acceptability up to fourteen (14) days after retrieval.

This policy does not affect the requirements in Section 52-3.4(c)(2) that all laboratory testing and donor medical history reports be reviewed and approved by the medical director or by the medical director's designee prior to release of tissue for distribution for clinical use. Further, this policy does not affect the Department's policy regarding distribution of birth tissues of January 21, 2022.